REMARKS

Applicants have studied the Office Action mailed July 6, 2006 and have made amendments to the claims. It is respectfully submitted that the application, as amended, is in condition for allowance. Reconsideration and allowance of the pending claims in view of the above amendments and following remarks is respectfully requested.

Rejection of claims 3 and 24-26 under 35 USC §103(a):

The Examiner rejected claims 3 and 24-26 under 35 USC §103(a) as being unpatentable over Baker et al. (Biochem. Biophys. Res. Comm. [1995] 213(1):154-160) in view of Campbell (Molecular Antibody Technology [1985] pp. 1-32).

In making this rejection, the Examiner states that, with respect to claim 3, the lanasterol synthase taught by Baker differs from instant SEQ ID NO:2 only by the deletion of an 11 amino acid residue segment in the instant disclosed SEQ ID NO:2 versus the longer polypeptide taught by Baker. The Examiner also states that, with respect to claim 24, a sequence comprising SEQ ID NO:2 encompasses the lanasterol synthase taught by Baker. The Examiner further states that Baker does not teach making monoclonal antibodies to lanasterol synthase, however Campbell teaches that "it is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it", and the Examiner asserts that it would have been prima facie obvious to make antibodies specific lanasterol synthase comprising the sequence of SEQ ID NO:2, and one would have been motivated, with a reasonable expectation of success, to generate monoclonal antibodies to the peptides. The Examiner also states that, while the lanasterol synthase protein taught by Baker is slightly longer than the instant disclosed SEQ ID NO:2, the artisan would reasonably expect that antibodies would be generated to epitopes distributed over the full length of lanasterol synthase and not just to the 11-amino acid segment of lanasterol synthase that is missing from SEQ ID NO:2, and there are no regions of instant SEQ ID NO:2 that are not present in the lanasterol synthase protein taught by Baker.

Applicants respectfully traverse these rejections under 35 USC §103(a) based on the following remarks.

First, claims 24 and 36 are hereby amended to recite a polypeptide comprising the contiguous amino acid sequence of SEQ ID NO:2, thereby rendering moot the Examiner's

assertion that, with respect to claim 24, a sequence comprising SEQ ID NO:2 encompasses the lanasterol synthase taught by Baker.

With regards to the other aspects of the rejection of claims 3 and 24-26 under 35 USC §103(a), the Examiner asserts, in effect, that antibodies which are produced as taught by Baker et al. and Campbell will inherently cross-react and thus bind to the same polypeptides (i.e., polypeptides comprising or consisting of SEQ ID NO:2) as the instantly claimed antibodies, thereby rendering obvious the instant claims. However, even assuming the references are combined as suggested by the Examiner, the combination still does not teach or suggest all the claim limitations, nor do the references address the problems solved by the claimed invention or appreciate its advantages. It is the claimed invention as a whole (e.g., antibodies that selectively bind to polypeptides comprising or consisting of SEQ ID NO:2) that must be evaluated against what is taught by the references.

It is Applicant's position that, for the rejection to be proper, an antibody produced as taught by Baker et al. and Campbell must necessarily cross-react and selectively bind to the polypeptides recited in the instant claims (i.e., polypeptides comprising or consisting of SEQ ID NO:2) in order for the references, as combined, to teach or suggest the claim limitations and to achieve the advantages and address the problems solved by the claimed invention. It is not sufficient that an antibody produced as taught by Baker et al. and Campbell may possibly or probably bind to the polypeptides recited in the instant claims.

However, this "possibly or probably" standard appears to be the standard that the Patent Office is relying on for the rejection of claims 3 and 24-26 under 35 USC §103(a). The Examiner has cited references that teach how to make an antibody that may possibly or probably selectively bind to proteins of SEQ ID NO:2 because the protein taught by Baker et al. differs from instant SEQ ID NO:2 only by the deletion of an 11 amino acid residue segment in instant SEQ ID NO:2 compared with the longer protein taught by Baker et al. (i.e., the protein taught by Baker et al. has an 11 amino acid residue insertion compared with instant SEQ ID NO:2), without demonstrating that an antibody produced as taught by Baker et al. and Campbell must necessarily selectively bind to proteins of SEQ ID NO:2.

It is Applicant's position that an antibody produced as taught by Baker et al. and Campbell does not necessarily selectively bind to proteins of SEQ ID NO:2 because different epitopes must

necessarily exist in the protein taught by Baker et al. compared with the protein of SEQ ID NO:2 because of the differences that exist in their amino acid sequences.

For example, the amino acid sequence of the protein taught by Baker et al. has an extra 11 amino acid residues compared with instant SEQ ID NO:2, and an antibody as taught by Baker et al. and Campbell could very well bind to an epitope that is contained wholly or partially within this extra 11 amino acid segment. In fact, there is no teaching or suggestion in Baker et al. or Campbell et al., or in the combination of these references, that would suggest that an antibody to the protein of Baker et al. should exclusively target the 721 amino acids that correspond to instant SEQ ID NO:2 (the protein of Baker et al. is 732 amino acids in length, which includes the extra 11 amino acid segment). Without this express teaching or suggestion, one of skill in the art who designed an antibody to the protein of Baker et al. may very well design an antibody that binds wholly or partially to the extra 11 amino acid segment of the protein of Baker et al., and such an antibody would not cross-react and bind with a protein of instant SEQ ID NO:2. It would not be obvious to limit the epitope to which the antibody binds to a region only within the 721 amino acids that correspond to instant SEQ ID NO:2, given only the protein of Baker et al. and in the absence of the instant application's express teaching of SEQ ID NO:2. Therefore an antibody produced as taught by Baker et al. and Campbell clearly does not necessarily bind to the same proteins (i.e., polypeptides comprising or consisting of SEQ ID NO:2) as the antibodies of claims 3 and 24-26.

Accordingly, Applicants respectfully request that the rejection of claims 3 and 24-26 under 35 USC §103(a) be reconsidered and withdrawn.

Rejection of claims 3 and 24-36 under 35 USC §103(a):

The Examiner rejected claims 3 and 24-36 under 35 USC §103(a) as being unpatentable over Baker et al. in view of Campbell and Harlow et al. (Antibodies: A Laboratory Manual. [1988] pages 72-77, 92-97, 128-135, 141-157, and 628-631).

In making this rejection, the Examiner states, in summary, that the combined references of Baker and Campbell do not teach antibody fragments. However, the Examiner states that Harlow further teaches the manufacture of Fab and $F(ab')_2$ fragments of monoclonclonal antibodies, and also teaches the conventional practice of labeling antibodies. The Examiner asserts that it would have been prima facie obvious to combine these references to produce

monoclonal antibodies to the protein, and one would have been motivated to do so, with a reasonable expectation of success. The Examiner also stated that claims 31-34 are included because any conventional diluent, such as water, physiological saline or PBS, would constitute such a "carrier" irrespective of the intended use.

In light of the discussion above in regards to the rejection of claims 3 and 24-26 under 35 USC §103(a) in view of Baker et al. and Campbell, it is clear that Baker et al. and Campbell, even in further view of Harlow et al., does not render obvious any of claims 3 and 24-36 due at least to the structural differences that exist in the protein taught by Baker et al. compared with the protein of SEQ ID NO:2 of the instant application. For example, the protein taught by Baker et al. has an additional 11 amino acid residues (compared with the protein of SEQ ID NO:2) at which an antibody could wholly or partially bind that would not be cross-reactive with instant SEQ ID NO:2, and there is no teaching in any of the references that suggests that an antibody to the protein taught by Baker et al. should be limited to binding outside of this 11 amino acid segment (thereby corresponding to the 721 amino acid length of instant SEQ ID NO:2). This obviates the teachings of Harlow et al. with respect to Baker et al. and Campbell as they apply to claims 3 and 24-36 under 35 USC §103(a).

Accordingly, Applicants respectfully request that this rejection under 35 USC §103(a) be reconsidered and withdrawn.

Conclusions

Claims 24 and 36 are hereby amended. As such, Claims 3 and 24-36 remain pending and under consideration. Claims 1-2 and 37-38 were withdrawn by the Examiner as being drawn to a non-elected invention.

In view of the above amendments and remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3812 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,
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